



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 2, 2006

MEMORANDUM:

Subject: EPA Reg. No.: 12455-56/Ditrac Tracking Powder
DP Barcode: D324638
Case No.: 2205

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Marianne Lewis 2/2/06

To: Venus Eagle, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Bell Laboratories, Inc.
3699 Kinsman Blvd.
Madison, WI 53704

FORMULATION FROM EPA Reg. No. 12455-56 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Diphacinone 2-(diphenylacetyl)-1,3-indandione	0.2%
<u>Inert Ingredient(s):</u>	99.8%
Total	100.0%

BACKGROUND: In the 8 month response to the Rodenticide RED, the registrant cited five (81-2, 81-3, 81-4, 81-5, 81-6) acute toxicity studies and submitted an acute oral study (81-1) to support the reregistration of their product, EPA Reg. No. 12455-56. The MRID's were as follows: 158435 (81-1), 158439 (81-2), 158440 (81-3), 158438 (81-4), 158437 (81-5), 158436 (81-6). The studies were conducted by Product Safety Labs and the test material used in each of the studies was the subject product. Four (81-2, 81-4, 81-5, 81-6) of the cited studies were found to be acceptable by PRB/SRRD on 8/6/03. The acute oral study (81-1) was found to be acceptable by PRB/SRRD on 8/6/03. The acute inhalation study (81-3) was found to be unacceptable by PRB/SRRD on 8/6/03.

The registrant has now submitted a new acute inhalation study (MRID # 466992-01. The study was conducted by Product Safety Labs and the test material used in the study was the subject product.

RECOMMENDATIONS:

- The acute inhalation study (81-3) submitted is acceptable to support the reregistration of EPA Reg. No. 12455-56.

The acute toxicity profile for EPA Reg. No. 12455-56 is currently:

Acute Oral	IV	Acceptable
Acute Dermal	II	Cited
Acute Inhalation	III	Acceptable
Primary Eye	IV	Cited
Primary Dermal	IV	Cited
Skin Sensitization	non sensitizer	Cited

NOTE: The labeling will be completed when all of the required information is received.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: John Hebert, 07
MRID No.: 466992-01

Reviewer: Marianne Lewis
Study Completion Date: 11/23/05
Report No.: 18542

Testing Facility: Product Safety Labs
Author: G. Moore

Quality Assurance (40 CFR §160.12): Included

Test Material: Ditrac Tracking Powder, brownish powder

Species: Sprague Dawley derived albino rat
Weight: males = 286 - 323 g; females = 202 - 235 g
Age: young adult
Source: Ace Animals, Inc.

Summary:

1. **LC₅₀ (mg/L):** > 0.52 mg/L

2. **MMAD:** 3.5 μ m

GSD: 1.97

3. **Tox. Category:** III

Classification: Acceptable

Procedure (Deviation From §81-3): none

Results: Reported Mortality

Exposure Concentration	(Number Deaths/Number Tested)		
	Males	Females	Combined
0.52 mg/L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level	MMAD	GSD
0.52 mg/L	3.5 μ m	1.94
	3.5 μ m	1.97

LABELING:

ID #: 012455-00056 **DITRAC TRACKING POWDER**

SIGNAL WORD: **WARNING**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

May be fatal if absorbed through skin. Harmful if inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing dust. Wear coveralls over short sleeved shirt and short pants, socks, chemical resistant footwear, and chemical resistant gloves (such as or made out of any waterproof material, selection category A).

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of an anticoagulant. The following statements are some suggested types of information that could be

Chamber Environment	Dose Level
	0.52 mg/L
Chamber Volume	6.7 L
Airflow	31.7 Lpm
Temperature (°C)	20 - 22
Relative Humidity (%)	42 - 50

Clinical Observations: All animals appeared active and healthy

Gross Necropsy Findings: No observable abnormalities were noted.

ACUTE TOX ONE-LINER

1. PC CODE: 067701
2. CURRENT DATE: February 2, 2006
3. TEST MATERIAL: Ditrac Tracking Powder, brownish powder
Diphacinone: 0.2%

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute inhalation toxicity/rat/ Product Safety Labs/18542/ 11-23-05	46699201	LC ₅₀ > 0.52 mg/L MMAD = 3.5 μ m; GSD = 1.97	III	A

Core Grade Key:

A = Acceptable

S = Supplementary (upgradeable)

U = Unacceptable

V = self-Validated

included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.